

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

**OUTSOURCING FACILITIES  
ASSOCIATION, ET AL.,**

Plaintiffs,

v.

**No. 4:24-CV-0953-P**

**UNITED STATES FOOD AND  
DRUG ADMINISTRATION,  
ET AL.,**

Defendants.

**IVIM HEALTH'S UNOPPOSED MOTION FOR LEAVE TO  
FILE BRIEF OF AMICUS CURIAE IN SUPPORT OF  
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

Brian Burgess  
D.C. Bar No. 1020915  
Goodwin Procter LLP  
1900 N Street, NW  
Washington, DC 20036  
T: (202) 346-4215  
F: (202) 346-4444  
bburgess@goodwinlaw.com  
*\*Pro Hac Vice* motion forthcoming

Maria Amelia Calaf  
Botkin Chiarello Calaf  
Texas State Bar. No. 24081915  
1209 Nueces Street  
Austin, TX 78701  
T: (512) 213-6094  
F: (737) 289-4695  
mac@bccauustin.com

Pursuant to Local Rule 7.2(b), Ivim Health respectfully seeks leave to file a brief of amici curiae, attached hereto as Exhibit A, in support of Plaintiffs' motion for preliminary injunction. *See* ECF Nos. 64-67. Pursuant to Local Rule 7.1(a) and (b), counsel for Ivim Health have conferred with counsel for all parties, who indicated that they do not oppose this motion.

Ivim Health is a medical institution that employs nearly 100 medical providers, including board certified physicians from the American Board of Obesity Medicine (ABOM) and nurse practitioners trained by obesity medicine staff, dedicated to the treatment and management of obesity, weight-related conditions, and overall optimization of health and wellness. Ivim Health has no financial interests or relationships with Eli Lilly, any other pharmaceutical company, the Outsourcing Facility Association (OFA), or North American Custom Laboratories, LLC. Ivim Health does not produce, manufacture, or dispense compounded medications, or own or operate any manufacturing facilities or pharmacies. Ivim Health's sole focus is on the well-being of patients, ensuring access to necessary treatments, and maintaining continuity of care for those patients currently relying on these treatments. Ivim Health respectfully seeks leave to file this brief as medical providers, in unwavering support of continued access for the patients reliant upon tirzepatide therapy whose health and wellness could be severely impacted by an adverse ruling on the Plaintiffs' motion.

FDA's action in removing tirzepatide from its shortage list affects patients with whom Ivim Health providers work and those patients' ability to safely access continued care. Ivim Health respectfully submits that its brief will provide the Court with unique insight into the issues presented in this litigation from the perspective of a medical institution that prescribes both branded and compounded medications. Ivim Health's real-world, clinical experience with adverse health impacts and other challenges due to inaccessibility of medications can provide practical context for the Court's understanding of Sections 503A and 503B of the Food, Drug, and Cosmetic

Act, the necessity for FDA to factor all stakeholders into a shortage decision, and the public interest in maintaining access to tirzepatide treatment.

For the foregoing reasons, Ivim Health respectfully requests that the Court grant its unopposed motion for leave to file the Brief of Amicus Curiae Ivim Health in Support of Plaintiffs' Motion for a Preliminary Injunction, attached hereto as Exhibit A.

Respectfully submitted,

February 4, 2025

*/s/María Amelia Calaf*  
Brian Burgess  
D.C. Bar No. 1020915  
Goodwin Procter LLP  
1900 N Street, NW  
Washington, DC 20036  
T: (202) 346-4215  
F: (202) 346-4444  
bburgess@goodwinlaw.com  
*\*Pro Hac Vice* motion forthcoming

María Amelia Calaf  
Botkin Chiarello Calaf  
Texas State Bar. No. 24081915  
1209 Nueces Street  
Austin, TX 78701  
T: (512) 213-6094  
F: (737) 289-4695  
mac@bccauustin.com

**CERTIFICATE OF CONFERENCE**

Pursuant to Local Rule 7.1(a) and (b), I certify that counsel for Amici conferred with counsel for both Plaintiffs and Defendants by email on January 31, 2025 and on February 3, 2025, to determine whether they oppose the relief sought by this Motion for Leave. Counsel for all parties informed counsel for Amici that they do not oppose the relief sought by this Motion.

*/s/ María Amelia Calaf*  
María Amelia Calaf

**CERTIFICATE OF SERVICE**

I certify that on February 4, 2025, the foregoing motion was electronically filed using the Court's electronic filing system, by which notice of this filing will be sent to all counsel of record.

*/s/ María Amelia Calaf*  
María Amelia Calaf